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510(k) Premarket Notification

Summary of Safety and Effectiveness Information

HBS™ Headless Bone Screw

December 14, 2001

Device Name:

Trade Name: **HBS™ Headless Bone Screw**
Common Name: Bone Screw
Classification Name: Smooth & threaded metallic bone fixation fasteners

Establishment Name & Registration Number:

Name: Millennium Medical Technologies, Inc. (MMT)
Number: Pending

Classification:

ProCode: HWC

Performance Standards (Section 514 compliance):

Food and Drug Administration mandated Performance standards for bone screws are not in effect. MMT intends to comply with all voluntary Performance Standards applicable to the **HBS™ Headless Bone Screw** system.

At the present time, The device is produced according to ISO 9001-2000 regulations covering medical devices. In addition, the materials used to construct the device meet ISO-5832-3,1996(E).

Special Controls:

All Class II devices are subject to Special Controls. No FDA mandated special controls are in effect at the present time.

Labeling:

The labeling of the device includes the following statements:

Warning: Federal (United States) Law restricts this device to sale by or on the order of a physician only.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The components of this system must NOT be used with implants of other material composition. Components of the **HBS™ Headless Bone Screw** should NOT be used with screws or components from any other system or manufacturer.

Equivalent Device(s):

HBS™ Headless Bone Screw may be directly contrasted with the following equivalent devices:

- **Zimmer HBS™**, Zimmer, Inc., K792022
- **Cannulated Navicular Screw**, Onyx Medical Corp. K931681

The Zimmer HBS is essentially identical (clinically speaking) to the **HBS™ Headless Bone Screw** in terms of basic design, features and intended use. The Onyx device is also very similar in design except that the Onyx device is indicated only for Navicular fractures, where as the MMT device has broader indications for use.

Description of the Device:

The **HBS™ (Headless Bone Screw)** and the mini **HBS™** are supplied as two series of cannulated bone screws varying in length and diameter. Both systems are intended for small bone applications and are thus considered a single system. Indeed, both systems are intended for use primarily in the hands and feet. The systems may be used for selected fractures elsewhere in the body so long as medically indicated and bone mass compatible.

Available screws and instrumentation are available as two individually boxed sets offered in the following sizes:

MINI HBS™

- 1.5mm shaft diameter, 3.2mm proximal thread diameter, 2.5mm distal thread diameter.
- 10mm through 30mm length in one millimeter increments.

Instrumentation:

- Handle for drill guide
- Drill guide
- Drill
- Drill handle
- T-Drive screw driver
- MBS Tray - Mini

STANDARD HBS™

- 3.0mm shaft diameter, 4.7mm proximal thread diameter, 4.0mm distal thread diameter.
- 10mm through 30mm length in one millimeter increments.

Instrumentation:

- Guide wire, 1mm
- Guiding handle for drill guide
- Drill guide
- Measuring sleeve
- Cannulated drill
- Cortical Drill
- Tap, standard compression
- Tap, high compression
- Cleaning wire
- Wire Dispenser
- Drill handle
- T-Drive screw driver
- Reduction Sleeve
- MBS Tray – Standard
- Container 300 x 300 x 140

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Intended Use: MINI

- Scaphoid fractures
- Lunate fractures
- Capitate
- Trapezial fractures
- Metacarpal and metatarsal fractures
- Phalangeal fractures
- Radial head fractures
- Ulnar styloid fractures
- Osteo-chondral
- Small joint fusions

Intended Use: STANDARD

- Scaphoid fractures
- Carpal fractures & non-unions
- Capitellum fractures
- Metacarpal fractures
- Phalangeal fractures
- Distal radial fractures
- Radial head fractures
- Ulnar styloid fractures
- Small joint fusions
- Humeral head fractures
- Glenoid fractures
- Intercarpal fusions
- Interphalangeal fractures
- Metatarsal osteotomies
- Tarsal fusions
- Malleolar fractures
- Patellar fractures
- Osteo-chondral fractures
- Odontoid fractures
- Mandibular fractures

MMT supplies instrumentation designed specifically to interface with this implant system. Drawings of necessary specialized instruments are included in Appendix II with the system engineering drawings.

The screws are made from titanium alloy. Material standard(s) are as specified in the table below:

TA6V ELI	ASTM F136-92	ISO 5832-3
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Summary of Biomechanical Testing:

Fixation characteristics of the screws were determined in both high compression and low compression modes. High compression mode yielded values in excess of 200N. Standard compression mode yielded values of 165N. In both instances, these values are in excess of values obtained with similar devices.

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Applicant / Sponsor Name / Address:

Millennium Medical Technologies, Inc.
460 St. Michaels Drive, Suite 901
Santa Fe, New Mexico, 87505
505.988.7595 – 505.988.7234 fax

Contact Person:

Mr. Fred Kolb
Millennium Medical Technologies, Inc.
460 St. Michaels Drive, Suite 901
Santa Fe, New Mexico, 87505
505.988.7595 – 505.988.7234 fax

Submission Correspondent:

Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 fax

Manufacturing Facility:

At the present time, the devices are contract manufactured in Europe and will be imported into the United States. The contract manufacturer is a recognized, registered manufacturer of implantable medical devices. The HBS screws are manufactured for MMT for distribution in the U.S.A.

Performance Standards:

There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as ASTM, various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the screws.

Sterilization, Packaging & Storage Information:

Sterilization. The **HBS™ Headless Bone Screws** and instruments are provided non-sterile and must be sterilized prior to use. The devices are clean and have been processed to remove debris and manufacturing residue.

The recommended sterilization process for the instruments is high temperature steam autoclave sterilization. The recommended sterilization cycle is: saturated steam at 270° F for 30 minutes. This is a typical or usual steam sterilization cycle used by hospitals for surgical devices and instruments. Use of this cycle produces a Sterility Assurance Level (SAL) of at least 10⁻⁶. Validation of the recommended sterilization cycle is completed. The following validated sterilization cycle is on file at MMT.

Method:	Steam
Cycle:	Gravity
Temperature:	270°F (134°C)
Exposure Time:	30 minutes

Packaging. Materials used in the production of the device are typical medical grade tubes, peel-type pouches of the generic mylar/non-woven sandwich variety, etc. All packages containing implants or instruments should be intact upon receipt.

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Comparison Table:

FEATURE	MMT HBS™	Zimmer HBS™	Onyx Navicular	SE?
Intended Use:	Scaphoid fractures Carpal fractures & non-unions Capitellum fractures Metacarpal fractures Phalangeal fractures Distal radial fractures Radial head fractures Ulnar styloid fractures Small joint fusions Humeral head fractures Glenoid fractures Intercarpal fusions Interphalangeal fractures Metatarsal osteotomies Tarsal fusions Malleolar fractures Patellar fractures Osteo-chondral fractures Odontoid fractures Mandibular fractures	Same	Navicular	Yes
Materials	Titanium	Same	Same	Yes
Lengths	10-30 mm in 1mm increments	10-30mm, 2mm	10-30mm	Yes
Diameters	Proximal thread 4.7mm (S) Proximal thread 3.2mm (M) Distal thread 4.0mm (S) Distal thread 2.5mm (M) Shaft Dia. 3.0mm (S) Shaft Dia. 1.5mm (M)	Prox. 4.5mm Distal 4.0mm	Unknown	Yes
Design	Headless, Threaded both ends	Same	Same	Yes
Sterilization	Steam	Steam	Steam	Yes
K-Number	Pending	792022	931681	Yes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 6 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Millennium Medical Technologies, Inc
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, CA 94523-3389

Re: K020791

Trade/Device Name: HBS™ Headless Bone Screw
Regulatory Number: 888.3040
Regulatory Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: March 7, 2002
Received: March 11, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

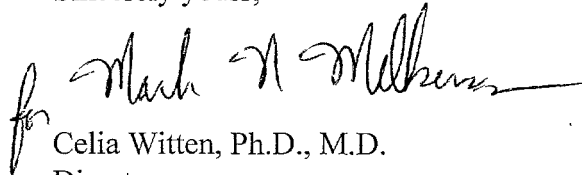
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. David W. Schlerf

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia Witten", with a stylized flourish at the end.

Celia Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

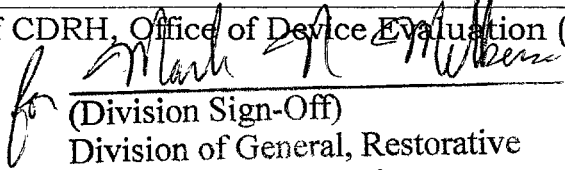
510(k) Number (if known): K020791Device Name: **HBS™ Headless Bone Screw****Indications For Use:**

Headless bone screw system for the fixation of osseous fragments or fractures including:

HBS - MINI	HBS - STANDARD
Scaphoid fractures Lunate fractures Capitate Trapezial fractures Metacarpal and metatarsal fractures Phalangeal fractures Radial head fractures Ulnar styloid fractures Osteo-chondral Small joint fusions	Scaphoid fractures Carpal fractures & non-unions Capitellum fractures Metacarpal fractures Phalangeal fractures Distal radial fractures Radial head fractures Ulnar styloid fractures Small joint fusions Humeral head fractures Glenoid fractures Intercarpal fusions Interphalangeal fractures Metatarsal osteotomies Tarsal fusions Malleolar fractures Patellar fractures Osteo-chondral fractures Odontoid fractures Mandibular fractures

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)

 Division of General, Restorative
 and Neurological Devices
510(k) Number K020791
 Prescription Use _____
 (Per 21 CFR 801.109)

OR

 Over-The-Counter Use _____
 (Optional format 1-2-96)